

## **REMARKS**

Claims 20-28, 31, and 32 are presently pending in the case. Claims 1-19, 29, 30, 33, and 34 have been cancelled. Claims 21-26 are withdrawn from consideration until such time as the generic claim from which they depend is determined to be allowable.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **After-Final Amendments**

Applicant has cancelled finally rejected claims 1-19, 29, 30, 33 and 34. The cancellation is made without prejudice or disclaimer, and Applicant reserves the right to pursue the cancelled claims in one or more continuing applications. By cancelling the aforementioned claims, Applicant has simplified the issues for appeal. Accordingly, entry of the amendment is requested. In addition, entry of the amendments is requested since all presently pending claims are in condition for allowance, as explained below.

### **Claim rejections under 35 USC §102**

The Examiner rejected claims 20, 27 and 28 under 35 USC §102(b) as being anticipated by U.S. Patent 4,069,819 to Valentini et al (hereinafter Valentini et al). The rejection is traversed.

Valentini et al does not anticipate independent claim 20, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 20 is to an aerosolization apparatus comprising, *inter alia*, a puncturing mechanism that comprises an alignment guide having a surface adapted to contact a capsule while a puncture member is

advanced into the capsule, and wherein the surface comprises one or more protrusions for contacting the capsule. This positively recited feature is not disclosed by Valentini et al. More specifically, Valentini et al does not disclose an alignment guide having a contact surface comprising one or more protrusions for contacting a capsule. The contact surface at the end of element L of Valentini et al contains no protrusions. Since Valentini et al does not disclose each and every feature set forth in claim 20, it does not anticipate the claim. Thus, the Examiner is respectfully requested to reconsider the language of claim 20 and withdraw the rejection thereof under 35 USC §102.

The comments made by the Examiner do not serve to establish Valentini et al as an anticipatory reference with regard to claim 20. On page 9 of the Final Office Action of October 16, 2007, the Examiner seems to consider the forward end of the contact surface to be a protrusion of the type claimed. However, this is an improper distortion of the reference and its teachings and does not satisfy the limitations positively set forth in claim 20. The contact surface of Valentini et al is the angled surface on which the capsule rests during puncturing of the capsule. There are no protrusions extending from *that* surface in Valentini et al. To say the forward end of the angled surface is a "protrusion" is no different than saying a flat tabletop comprises protrusions because of its four edges. Furthermore, the forward end of the surface of Valentini et al does not serve to satisfy the claim limitations because the forward end does not contact the capsule. Moreover, as required by the claim 20, the contact surface is defined as the surface that contacts the capsule during the puncturing of the capsule. As can be seen in Figure 5 of Valentini et al when the holes in the capsule are aligned with the puncturing members, the portion of the surface that contacts the capsule does not comprise any protrusions. For at least these reasons, Valentini et al does not anticipate claim 20.

Applicant requests withdrawal of the rejection of claim 20 under 35 U.S.C. §102(b). In addition, Applicant requests allowance of claims 21-28 which depend from claim 20 and are not anticipated by Valentini et al for at least the same reasons as claim 20.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 30 and 31 under 35 USC §103(a) as being unpatentable over Valentini et al in view of Published US Patent Application 2003/0000523 to Citterio (hereinafter Citterio). The rejection is traversed.

Valentini et al and Citterio do not render claims 30 and 31 unpatentable. Claim 30 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, *inter alia*, contacting a capsule with the surface of an alignment guide, the surface comprising one or more protrusions for contacting the capsule, and advancing a puncture member through the wall of the capsule to create an opening in the capsule. Valentini et al does not teach contacting a capsule with a surface comprising one or more protrusions. Citterio is cited by the Examiner for allegedly teaching a removable end section. Thus, Citterio does not teach, nor is it alleged to teach, a surface with a protrusion, as claimed in claim 30. Therefore, Citterio fails to make up for the deficiencies of Valentini et al. Accordingly, Valentini et al and Citterio fail to disclose or suggest all positively recited limitations, and the Examiner has failed to establish a *prima facie* case of obviousness under 35 USC 103(a).

For at least these reasons, claim 30 is not properly rejectable under 35 USC §103(a) as being unpatentable over Valentini et al and Citterio. A modification that would result in the invention claimed in claim 30 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no showing or allegation that the modification could be applied, with a reasonable likelihood of success, to Valentini et al. There is no evidence to suggest that this is a situation where the ordinary artisan would have seen the benefit of making the modification. Furthermore, Applicant has unexpectedly found that by providing the protrusion, the efficiency of the device is increased and the lifetime of the device is extended, as discussed on page 11 lines 19-30 of the specification. Thus, claim 30 is

allowable over the references cited.

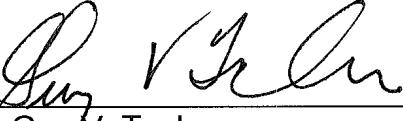
Applicant requests withdrawal of the rejection of claim 30 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claim 31 which depends from claim 30 and is not rendered unpatentable by Valentini et al and Citterio for at least the same reasons as claim 30.

## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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